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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,842	06/18/2001	Stanley Stein	601-1-097 N	9975

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EXAMINER
DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/883,842	STEIN ET AL.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1, 2, 4-7,9, 11, 13, 14, 17-27, 29, 30, 34, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Wallace et al. (U.S. Patent 6,312,725).

The claimed invention refers to compositions comprising two or more phases, a therapeutic agent and a crosslinked polymer, methods of preparing, delivering or administering said composition, and to a hydrogel composition.

Wallace et al. discloses two-component polymer compositions, that react together to form a matrix at the site of administration, and teaches that both components have multiple functional groups (See col. 1, line 65 to col. 2, line 11). Wallace et al. teaches that preferably both components are polymers, with the core of the polymer being polyethylene glycol (PEG), and the linkage formed between the two components may be a thioester, thioether or disulfide (See col. 2, lines 12-37). Wallace et al. provides a method of treating tissue for the purpose of drug delivery, comprising mixing the two components at the site of administration (See 2, line 55 to col. 3, line 4). Wallace et al. includes ortho pyridyl disulfide in the presence of hydrogen peroxide, iodoacetamide, maleimides and vinylsulfones among the reagents used to facilitate

bond formation (See col. 6, lines 41-67). Wallace et al. includes optional materials in the compositions, such as proteins, drugs, cells and therapeutic agents, which may become covalently incorporated into the matrix, and teaches that one of the components may be in the form of dry powder and the other is in liquid form (See col. 7, line 61 to col. 8, line 50). Wallace et al. teaches that the compositions of the invention can be locally administered using various methods and used in different pharmaceutical applications, in particular controlled release drug delivery (See col. 9, line 45 to col. 11, line 2).

The compositions and methods disclosed by Wallace et al. meet the limitations of claims 1, 2, 4-7, 9, 11, 13, 14, 17-27, 29, 30, 34, 36 and 37 of the instant application, as they contemplate compositions comprising two or more phases, a therapeutic agent and a crosslinked polymer, methods of preparing, delivering or administering said composition, and a hydrogel composition. Thus, Wallace et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. in view of Grinstaff et al. (U.S. Patent 5,498,421).

The teachings of Wallace et al. have been summarized above. Wallace et al. is deficient in the fact, that it does not specifically disclose the compositions in the form of emulsion and does not provide the kinetic profile of drug release from the compositions of the invention.

Grinstaff et al. provides compositions for in vivo delivery of solid or liquid active agents contained in crosslinked polymeric shells, through several routes of administration, including oral, subcutaneous, itraperitoneal and transdermal (See col. 7, line 60 to col. 8, line 33). Grinstaff et al. includes linear and branched PEGs among the synthetic polymers used in the invention, and teaches that the active agent may be dispersed in oil and the polymeric shells containing the active agent may be suspended in an aqueous medium to form lipid-containing emulsions (See col. 9, line 14 to col. 10, line 2). Grinstaff et al. teaches that the polymeric shell can be modified by forming a covalent bond with crosslinked polymers, such as PEG derivatives, including PEG-thiols (See col. 12, line 14 to col. 13, line 27). Grinstaff et al. teaches that the compositions of the invention are suitable for delayed or controlled release of an entrapped pharmaceutical agent (See Example 5).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions disclosed by Wallace et al., by providing said compositions in the form of emulsions, as taught by Grinstaff et al., to device controlled or delayed release compositions of drugs, which are insoluble in water. The expected result would have been a successful controlled release composition and successful methods of preparing, delivering or administering said compositions. Because of the teachings of Grinstaff et al., that

water-insoluble drugs can be dispersed in oil and included in polymeric shells suspended in an aqueous phase, and the compositions are suitable for controlled or delayed release, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

LDNB

September 12, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600